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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/374,142 08/11/99 LIN

H P07-42146

EXAMINER

HM22/0322

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REMARK, J
ART UNIT PAPER NUMBER

1644
DATE MAILED:

03/22/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/374,142

Applicant(s)

LIN ET AL.

Examiner

Jessica H. Roark

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 January 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-66 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 1-66 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

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DETAILED ACTION

Restriction Requirement

1. Please Note: In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-308-4315. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Paula Hutzell, Ph.D., Supervisory Patent Examiner at Paula.Hutzell@uspto.gov or 703-308-4310. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

2. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1-11, drawn to a method of diagnosing a disease corroborated by the presence of SIBO, classified in Class 436, subclass 811.

II. Claims 12-30 and 56-66, drawn to a method of treating a disease involving SIBO by eradicating the SIBO, classified in Class 514, subclass 885.

III. Claims 31-55, drawn to a kit for detecting and treating diseases related to SIBO comprising a sugar substrate and a breath sampling container, classified in Class 435, subclass 810.

3. Groups I and II are different methods. A method of diagnosing and a method of treating differ with respect to ingredients, method steps, and endpoints; therefore, each method is patentably distinct.

4. Groups III and I/II are related as product and process of using. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the kit of Group III can be used in each of the methods recited.

5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and recognized divergent subject matter, restriction for examination purposes as indicated is proper.

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Species Election

6. This application contains claims directed to the following patentably distinct species of the claimed Inventions I/II/III: wherein the disease is:

- A) IBS and Crohn's disease,
- B) fibromyalgia,
- C) chronic fatigue syndrome,
- D) depression,
- E) ADHD, or
- F) an autoimmune disease (subspecies election required, see below).

These species are distinct because these conditions differ in pathophysiologies and patient populations; thus each condition represents patentably distinct subject matter.

In addition, since F) "an autoimmune disease" is a genus rather than a true species; if Applicant elects F) then Applicant must elect a further subspecies directed to the following patentably distinct subspecies of claimed autoimmune disease:

- i) MS, or
- ii) SLE.

These subspecies are distinct because the conditions differ in pathophysiologies and patient populations; thus each condition represents patentably distinct subject matter.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, 12, and 31 are generic.

7. This application contains claims directed to the following patentably distinct species of the claimed Inventions II: wherein the at least partial eradication of SIBO is accomplished using:

- A) an antimicrobial agent,
- B) a probiotic agent,
- C) intestinal lavage or enema,
- D) a modified diet, or
- E) a prokinetic agent.

These species are distinct because their structures and modes of action differ; therefore they are patentably distinct.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 12 is generic.

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8. This application contains claims directed to the following patentably distinct species of the claimed Inventions II: wherein the method of treating further comprises:

- A) no additional active ingredients,
- B) a pro-inflammatory cytokine antagonist,
- C) an anti-inflammatory cytokine or an agonist thereof, or
- D) an agent that modifies afferent neural feedback or sensory perception.

These species are distinct because the active ingredients differ with respect to both structure and mode of action; therefore they are patentably distinct.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 12 is generic.

9. This application contains claims directed to the following patentably distinct species of the claimed Inventions III: wherein the kit comprising a sugar substrate and a breath sampling container is for:

- A) diagnosis, or
- B) treatment.

If Applicant elects a kit for treatment, then Applicant is further required to elect one of the recited agents which the kit may further comprise:

- A) an antimicrobial agent,
- B) a probiotic agent,
- C) a prokinetic agent.
- D) an antagonist of a proinflammatory cytokine, or
- E) an agent that modifies afferent neural feedback or sensory perception.

These species are distinct because their structures and modes of action differ; therefore they are patentably distinct.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 31 is generic.

10. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

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11. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessica Roark whose telephone number is (703) 605-1209. The examiner can normally be reached Monday through Friday from 8:00 AM to 4:30 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Jessica Roark, Ph.D.
Patent Examiner
Technology Center.1600
March 21, 2001

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3/21/01